REMARKS

In the Office Action, the Examiner rejected pending claims 1-16 under 35 USC 103(a) as being unpatentable over the combination of Jackson in view of Orsonneaau and Boguslaski and under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claims the subject matter which applicant regards as the invention. Applicant respectfully traverses these rejections in view of the following remarks.

Rejection under 35 USC 103(a)

The Examiner asserts that Jackson teaches a test kit with a first substrate containing urea, and a separate substrate containing a pH dye for testing biopsy specimens, and a well with a single test composition containing the urea and dye indicator. The Examiner indicates that the claims of the present invention differ from Jackson in that the present claims recite the specimen is first contacted with urea, and then contacted with an indicator where the two components are separate. However, the Examiner asserts that Orsonneau teaches contacting biological fluids with a pH dye and a urea in separate steps while Boguslaski teaches a test strip having two components, one containing a urease substrate and the other containing a pH indicator. The Examiner concludes that it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the dual components of each of Orsonneau and Boguslaski in the method of Jackson because the secondary references teach separating the urea and indicator where Jackson teaches all the features of the present invention but with two regents in a single composition, and that separating reagents would have the

expected results as taught by Boguslaski of permitting optimized compositions and increased sensitivity.

While Jackson does teach testing biopsy specimens using a first substrate containing urea and a second substrate containing a pH dye, Jackson does not teach a method including two wells for separating the first and second substrates and further does not teach using isolated urea in a powder form to increase stability of the testing compositions. As indicated in the specification of the present invention at page 6, lines 13-17 and in the Example set forth on pages 12-13, the stability of the testing composition is critical to the present invention. Claims 1 and 2 of the present invention have been amended above to emphasize the importance of the powder urea.

Jackson specifically teaches away from the present invention in that it teaches, at column 2, lines 41 and 43, using a "gelled test composition" containing urea and a pH dye. Such gelled compositions are what the present invention does not want as indicated in the specification at page 12, line 20 through page 13, line 10, where Applicant points out the inferior stability of gelled compositions as compared to the powder composition of the present invention. Neither Orsonneau nor Boguslaski overcome the shortcomings of Jackson because they neither, alone nor combined, teach or suggest using a two-well testing method wherein the first composition is comprised of powder urea. Accordingly, Applicant respectfully requests that the rejection of claims 1-16 be withdrawn.

Further, Orsonneau only suggests a method of measuring the concentration of urea or urease in a fluid by mixing the fluid with a pH dye and then mixing the fluid with urea or urease. Orsonneau does not suggest using a two well testing method to determine the presence of urease, nor does it indicate a stable and effective isolated powdered urea.

Boguslaski discloses using a strip of an absorbent paper matrix, half of which contains a dried urea residue and half of which contains a dried pH sensitive indicator residue, to detect Helicobacter Pylori. Boguslaski does not suggest a powder form of urea for use in detecting urease, and further does not suggest that a dry particle matrix urea and a powder urea would have the same properties. While the urea and pH indicator of Boguslaski are isolated from each other on one strip, Boguslaski does not suggest using two wells and a process of contacting the material with urea and then pH indicator. Rather Boguslaski relies on the permeation of ammonia through the buffer from one side of the strip to the other. There is no suggestion that a two step contact process using powdered urea would be successful.

Given the above remarks, Applicant believes that neither Boguslaski nor Orsonneau overcome the lack of disclosure of Jackson, and, accordingly, Applicant respectfully requests that the rejection of Claims 1-16 be withdrawn.

Rejection Under 35 USC 112

The Examiner rejects Claims 1-16 under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner sets forth that it is improper to address urea as "being capable of" because compounds do not have capabilities. Applicant submits that the above amendments to claims 1 and 16 overcome this rejection by removing the language "being capable of". Accordingly, Applicant respectfully requests that this rejection be withdrawn.

Objection to Title of Invention

The Examiner also objected to the title of invention as not being aptly descriptive of the invention. Applicant submits that the above amendment to the specification changing the title to A STABLE DIAGNOSTIC TESTING SYSTEM AND METHOD FOR DETECTING *HELICOBACTER PYLORI* IN THE GASTROINTESTINAL SYSTEM.

CONCLUSION

In view of the above amendments and remarks, Applicant submits that the rejections and objections to the claims and specification have been overcome and the application is now in condition for allowance. Accordingly, Applicant respectfully requests that the rejections be withdrawn and the application be allowed.

Respectfully submitted,

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